

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MDL Docket No. 1629
MARKETING, SALES Master File No.
PRACTICES and PRODUCTS 04-10981
LIABILITY LITIGATION Judge Patti B. Saris
 Magistrate Judge
 Leo T. Sorokin

RUTH SMITH,

Plaintiff, C. A. No. 05-11515
v.

PFIZER, INC., et al.,

Defendants.

Videotaped Deposition of:

EDWARD MACKEY, M.D.

Wednesday, May 23, 2007

1
2 **STIPULATIONS**
3 It is stipulated and agreed, by
4 and between the parties through their
5 respective counsel, that the videotaped
6 deposition of:

7 EDWARD MACKEY, M.D., may be
8 taken before Fred W. Jeske, court reporter and
9 Tennessee Notary Public, at the offices of
10 Miller & Martin, 1200 US Bank Tower, 150 Fourth
11 Avenue, North, Nashville, Tennessee, on
12 Wednesday, May 23, 2007, commencing at
13 approximately 8:40 a.m.

14 It is further stipulated and
15 agreed that the signature to and reading of the
16 deposition by the witness is waived, the
17 deposition to have the same force and effect as
18 if full compliance had been had with all laws
19 and rules of Court relating to the taking of
20 depositions.

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15 Also present:
16 Jonathan Wilkerson, law clerk
17 Sheldon Singh, videographer
18 -oOo-

1
2 It is further stipulated and
3 agreed that it shall not be necessary for any
4 objections to be made by counsel to any
5 questions, except as to form or leading
6 questions, and that counsel for the parties may
7 make objections and assign grounds at the time
8 of the trial, or at the time said deposition is
9 offered in evidence, or prior thereto.

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1 VIDEOGRAPHER: My name is
 2 Sheldon Singh of Nationwide Video
 3 Productions, Inc., located in Roseland, New
 4 Jersey.

5 Today's date is Wednesday, May
 6 23rd, 2007, and the time on the monitor is
 7 8:40 a.m. This deposition is being held in
 8 the office of Miller and Martin, located at
 9 150 Fourth Avenue, North, Nashville,
 10 Tennessee, 37219.

11 The caption of this case is
 12 Neurontin Marketing, Sales Practices and
 13 Products Liability Litigation, Ruth Smith
 14 v. Pfizer, Inc., et al.

15 The case number is 05-11515, in
 16 the United States District Court, District
 17 of Massachusetts.

18 The name of the witness is
 19 Dr. Edward S. Mackey.

20 At this time the attorneys will
 21 identify themselves and the parties they
 22 represent after which our court reporter,
 23 Mr. Fred Jeske, of Vowell & Jennings, will
 24 swear in the witness so we can proceed.

25 MR. LANIER: My name is Mark

1 middle of the day to come down to the
 2 courthouse to testify. But we do recognize you
 3 taking time today, and we appreciate it.

4 I have a copy of what's your
 5 curriculum vitae, kind of a resume type thing.
 6 I'm marking it as Exhibit 1.
 7 (Exhibit 1 marked.)

8 Q. Would you confirm for the jury that
 9 that's who you are.

10 A. Yes.

11 Q. Thank you. And then we have brought --
 12 you have brought today a copy of your medical
 13 records on Mr. Smith. We're going to mark that
 14 as Exhibit 2 and we'll attach that as well.

15 (Exhibit 2 marked.)

16 Q. Is that a full and complete copy of
 17 those records, sir, to the best of your
 18 knowledge?

19 A. I, I believe so.

20 Q. Okay. I assume you didn't make the
 21 copies yourself personally but you asked for a
 22 copy to be made?

23 A. That is correct.

24 Q. All right. Thank you. Please feel
 25 free to refer to that as you need to throughout

1 Lanier. I'm here with a number of folks
 2 representing the Smith family. I've got
 3 from my office Bob Leone, Andrew
 4 Finkelstein from his office is here, along
 5 with Keith.

6 We've got Dara Hegar. We've got
 7 Patrick O'Hara, and we've got -- and we
 8 have got Jonathan Wilkerson here from our
 9 office.

10 MR. FERGUSON: Ken Ferguson,
 11 Clark, Thomas and Winters, in Austin, Texas
 12 for Pfizer, Parke-Davis and Warner-Lambert
 13 along with Cedric Evans from the same firm.

14 MR. STAHL: I'm Noel Stahl. I'm
 15 here with Dr. Ed Mackey.

16 EDWARD MACKEY, M.D.,
 17 having been duly sworn, testified as follows:

18 DIRECT EXAMINATION

19 BY MR. LANIER:

20 Q. Dr. Mackey, thank you for taking time
 21 to be with us today. We appreciate it.

22 We have an opportunity to take
 23 your deposition by videotape so that a jury's
 24 able to listen and watch your testimony, and
 25 you don't have to stop your practice in the

1 the deposition, and we'll try not to take too
 2 much of your time today.

3 First a little bit about you.

4 What kind of doctor are you?

5 A. I'm an orthopedic surgeon.

6 Q. In everyday language what's an
 7 orthopedic surgeon?

8 A. It's a doctor specializing in the care
 9 of bones and muscles of the body.

10 Q. If I have got a problem with my back,
 11 are you the kind of doctor I'd go see?

12 A. Yes.

13 Q. Okay. Did you have a chance to look at
 14 and take care of some Richard Smith?

15 A. Yes.

16 Q. And that's the gentleman whose chart
 17 you have in front of you; right?

18 A. Yes.

19 Q. What, if you could tell the jury, is
 20 the time period when you gave your care for
 21 Mr. Smith?

22 A. I first saw Mr. Smith February 12th,
 23 2004.

24 Q. And so that we get the other bookend in
 25 place, when was your last time to see

1 A. Yes, I do.
 2 Q. Sir, Neurontin is the drug that we're
 3 discussing; right?
 4 A. Yes.
 5 Q. Now you're not a pharmacist yourself?
 6 A. No.
 7 Q. And I assume that you've got a full
 8 slate of patients, so you spend most of your
 9 time trying to treat people and help them get
 10 well and doing surgery?
 11 A. Yes.
 12 Q. You're not a drug researcher who is out
 13 there doing independent research to figure out
 14 what drugs do and how they do it, are you?
 15 A. No.
 16 MR. FERGUSON: Object to form.
 17 A. No.
 18 Q. (By Mr. Lanier) Have you ever had a
 19 chance to look at the actual label for
 20 Neurontin, yourself? And let me, let me
 21 preface that by giving you a copy. So -- I'm
 22 sure you've glanced at it or something, but I
 23 want to ask you some questions about it. So
 24 we'll mark it as Exhibit 4.
 25 A. Okay.

1 (Exhibit 4 marked.)
 2 Q. And I will represent to you this is a
 3 copy of the label at the time that you had
 4 prescribed it for Mr. Smith. And ask you to
 5 take a moment and just sort of look at it. I'm
 6 going to specifically direct your attention to
 7 the indications, on page 10 of this copy.
 8 A. Yes.
 9 Q. Do you have that in front of you?
 10 A. I do.
 11 Q. Now there are two indications that
 12 Pfizer has given for their drug, one is for
 13 postherpetic neuralgia, which I understand
 14 means the management of shingles pain; is that
 15 right?
 16 A. Yes.
 17 Q. Obviously you weren't prescribing this
 18 for shingles, were you?
 19 A. No.
 20 Q. The second is for epilepsy, partial
 21 seizures. Do you see that as well?
 22 A. I do.
 23 Q. And I assume you were not prescribing
 24 this for epileptic reasons either.
 25 A. No.

1 Q. Sir, those are the only two indications
 2 that the FDA allowed Pfizer to put into their
 3 label. Do you see that?
 4 A. Yes.
 5 Q. I want to ask you some questions about
 6 what your knowledge was about what Pfizer was
 7 doing off label as far as their drug, so I'm
 8 going to ask you a series of questions here,
 9 and I will try and provide you the information.
 10 I want to see if this is information that you
 11 had even found out yourself, okay?
 12 MR. FERGUSON: Object to form.
 13 Q. (By Mr. Lanier) Did you know that
 14 over 90, 90 percent of Pfizer's sales for
 15 Neurontin were for off-label uses?
 16 MR. FERGUSON: Object to form.
 17 A. I knew it at some point. I don't know
 18 when I knew that.
 19 Q. (By Mr. Lanier) And by off-label uses,
 20 you understand we're talking about
 21 prescriptions being written to use the drug for
 22 reasons that the FDA never approved in the
 23 label; right?
 24 A. Yes.
 25 Q. Did you know that on the very day of

1 Mr. Smith's death that Pfizer filed with a
 2 court a plea agreement basically setting
 3 forward the fact that they had not been
 4 following the law on the way they were
 5 marketing their drug?
 6 MR. FERGUSON: Object to form.
 7 Q. (By Mr. Lanier) Did you know about
 8 that?
 9 A. Um, yes. That was widely reported in
 10 the news.
 11 Q. Okay. Didn't know about it beforehand,
 12 that it had been going on, but once it happened
 13 you found out about it, is that fair to say?
 14 MR. FERGUSON: Object to form.
 15 A. I don't recall exactly what I knew at
 16 what point, but I certainly knew after the
 17 lawsuit was discussed or settled.
 18 Q. Okay.
 19 A. The issues.
 20 (Exhibit 5 marked.)
 21 Q. (By Mr. Lanier) If you'll look at
 22 Exhibit 5. It's a legal pleading, we call it
 23 an information, but it basically sets up the
 24 ultimate plea agreement with the court. And
 25 you can go to the very last page of it, page

1 abstracts and case reports in promoting
 2 Parke-Davis's prescription drugs, including
 3 Neurontin, for a variety of medically
 4 unacceptable uses. Do you see that as well?
 5 A. Yes.
 6 Q. Sir, as a doctor, is it important to
 7 you that drug companies put patient safety
 8 first?
 9 A. Yes.
 10 Q. Is it important to you that drug
 11 companies follow FDA instructions and rules and
 12 guidelines --
 13 MR. FERGUSON: Object to form.
 14 Q. -- about what they're telling you and
 15 what they're not?
 16 A. Yes.
 17 Q. (By Mr. Lanier) Now if you had been
 18 told either in the labeling information or
 19 through sales reps or, Dr. Mackey, through your
 20 partners, if you had been told that Neurontin
 21 was a drug with some of the problems we've
 22 talked about so far today, would it have
 23 changed the way you treated Mr. Smith?
 24 MR. FERGUSON: Object to form.
 25 A. Possibly. Probably.

1 Q. All right. How did you find out about
 2 his death?
 3 A. His wife called our office and spoke
 4 with our telephone answering operator and then
 5 spoke with my nurse.
 6 Q. Okay. Did you by any chance file a
 7 MedWatch report with the FDA after this, do you
 8 know?
 9 A. I don't know. I don't think I've
 10 ever -- I don't know to do that or --
 11 Q. Yeah. I didn't think so, but I didn't
 12 see one, and I just wasn't sure.
 13 MR. LANIER: I'm going to, I've
 14 used 45 of my minutes. I'm going to save
 15 my other 45. I'm going to pass the witness
 16 and see if he can really do it in 44.
 17 MR. FERGUSON: Doctor, are you
 18 doing okay? Do you need a break or
 19 anything?
 20 THE WITNESS: I'm okay.
 21 CROSS-EXAMINATION
 22 BY MR. FERGUSON:
 23 Q. Dr. Mackey, we met briefly before the
 24 deposition. My name is Ken Ferguson. I
 25 represent Pfizer in this matter. Do you

1 Q. (By Mr. Lanier) Probably. And by
 2 probably, would it have meant you would have
 3 either tried another drug first, or would you
 4 have at least put out some warnings and some
 5 safeties and precautions and told them what to
 6 be observant about?
 7 MR. FERGUSON: Object to form.
 8 A. Certainly I would have done the
 9 latter.
 10 Q. Okay.
 11 A. And I don't know about the former.
 12 Q. (By Mr. Lanier) All right. Now if
 13 someone's at risk of -- I don't know that you
 14 see often someone that you consider a suicide
 15 risk in your practice, but if you see someone
 16 that presents that you think is a serious
 17 candidate for suicide, I would assume you would
 18 do something about that. There is some
 19 protocol.
 20 A. Yes.
 21 Q. Okay. Mr. Smith, when he presented to
 22 you, I've read through your chart, there's
 23 nothing about him that made you think he was a
 24 suicide risk when he presented, was there?
 25 A. No.

1 understand that?
 2 A. Yes.
 3 Q. Doctor, you graduated from Dartmouth
 4 undergrad; correct?
 5 A. Yes.
 6 Q. And you went to Vanderbilt University
 7 Medical School right here?
 8 A. Yes.
 9 Q. You're board certified in orthopedic
 10 surgery?
 11 A. I am.
 12 Q. You're board certified in spine surgery
 13 also; correct?
 14 A. Yes.
 15 Q. Generally, do you make your own
 16 decisions about how you treat your patients?
 17 A. Yes.
 18 Q. Nobody's going to tell you how to treat
 19 your patients, are they?
 20 A. No.
 21 Q. I want to follow up a bit on some of
 22 the care and treatment you actually performed
 23 on Mr. Smith, if I could, okay?
 24 Mr. Lanier spoke about that
 25 briefly. Let me ask you some questions.

1 you that I recall for sure, --
 2 Q. Um-hum.
 3 A. -- that I had samples in my closet for
 4 distribution to patients.
 5 Q. Okay. And did you distribute those
 6 samples?
 7 A. I did.
 8 Q. And those samples are always
 9 accompanied by their product labeling, aren't
 10 they?
 11 A. I believe so. I think each box comes
 12 with one.
 13 Q. We talked about the fact that Lortab or
 14 narcotic pain relievers have potential for
 15 addictive behavior. To your knowledge, does
 16 Neurontin have potential for addictive
 17 behavior?
 18 A. I'm not aware of it.
 19 Q. Do some medications have the potential
 20 to damage the liver, because they're
 21 metabolized through the liver?
 22 A. Yes.
 23 Q. Do you know if Neurontin fits that
 24 category or not?
 25 A. I believe it goes through the kidney.

1 A. A long time ago, probably.
 2 Q. There was a lot of discussion on the
 3 prior examination regarding off-label use
 4 versus on-label use. Do you understand that
 5 distinction?
 6 A. Quite well.
 7 Q. And really off-label use can, can
 8 include indications that aren't labeled;
 9 correct?
 10 A. Right.
 11 Q. Off-label use can also include for --
 12 in dosages not labeled; correct?
 13 A. I didn't realize that as well, but yes,
 14 that makes sense.
 15 Q. Okay. Is it uncommon or common for
 16 doctors to prescribe medications for unlabeled
 17 indications?
 18 A. I, I imagine it's relatively common. I
 19 don't know to what extent it is.
 20 Q. Okay. Is Neurontin the only medication
 21 you have ever prescribed off-label?
 22 A. I don't know.
 23 Q. Do you know whether or not the FDA
 24 recognizes and even approves the prescription
 25 of drugs off-label?

1 Q. And you noted that you had had success
 2 with Neurontin with other patients prior to
 3 Mr. Smith?
 4 A. Yes.
 5 Q. And you have had success with Neurontin
 6 since prescribing for Mr. Smith.
 7 A. Yes.
 8 Q. Was the fact that you had had success
 9 in treating other patients with Neurontin a
 10 factor in making the decision to prescribe for
 11 Mr. Smith?
 12 A. Among others, yes.
 13 Q. Other than the discussions that you
 14 think may have taken place, probably took place
 15 with sales representatives, did you receive any
 16 other information from any source of Pfizer,
 17 Warner-Lambert, Parke-Davis regarding the use
 18 of Neurontin, that you recall?
 19 A. Not that I recall.
 20 Q. And I think Mr. Lanier asked you this,
 21 but I can't recall exactly what your answer
 22 was. With regard to the PDR information, the
 23 labeling information regarding Neurontin, had
 24 you reviewed that at some point prior to
 25 prescribing for Mr. Smith?

1 A. Um, again, I don't know.
 2 Q. Okay. Does the FDA try to --
 3 MR. STAHL: Four minutes.
 4 MR. FERGUSON: Thank you.
 5 Q. (By Mr. Ferguson) Does the FDA ever,
 6 to your knowledge, try to tell doctors how to
 7 practice medicine?
 8 A. No.
 9 Q. During the period of time that you --
 10 you said you may have reviewed the Neurontin
 11 label sometime prior to having prescribed for
 12 Mr. Smith. Do you re-review labeling on an
 13 annual basis or on any kind of a regular basis
 14 or not, on medications that you prescribe
 15 regularly?
 16 A. Ah, not typically.
 17 I guess, you know, those type of
 18 updates or changes I sort of rely on
 19 information coming to me.
 20 Q. Do you know one way or the other
 21 whether in the label in, say, 2003-2004 time
 22 frame, there was any information in the label
 23 regarding suicidal behavior or suicidal
 24 gesture?
 25 A. Do I -- did I know that in 2004?

1 Q. Yes, sir.
 2 A. No, I did not.
 3 Q. As you sit here today, do you know
 4 whether or not there was --
 5 A. Yeah.
 6 Q. -- such information in the label back
 7 in 2003-2004?
 8 A. Yes. Among many other issues.
 9 Q. As -- and if I'm getting out your area
 10 you just let me know. But as someone who
 11 treats chronic pain patients, and I realize you
 12 treat them for certain, in certain situations.
 13 And you would have your colleagues in your
 14 office treat other kinds of chronic pain. But
 15 you do treat chronic pain patients; correct?
 16 A. Um, if they're -- if I can manage them
 17 surgically, I will.
 18 Q. Um-hum.
 19 A. If I cannot, I sent them out to someone
 20 who does that.
 21 Q. Do you know one way or the other
 22 whether individuals who have long-term chronic
 23 pain are more likely or less likely to commit
 24 suicide than the normal population?
 25 A. You're right, I think you're outside my

1 in the 2003-2004 time frame there was some
 2 information about suicidal conduct, suicidal
 3 gesture in the, the Neurontin labeling;
 4 correct?
 5 A. It's in the PDR, 2004.
 6 Q. Right. When did you become aware of
 7 that?
 8 A. Preparing for this deposition.
 9 Q. And the fact of that was in there,
 10 that's not keeping you from prescribing
 11 Neurontin to anybody, is it?
 12 A. I wouldn't say to anybody, but it has
 13 not -- I still will prescribe it.
 14 Q. Okay. Are you aware of any, any
 15 labeling changes that took place with regard to
 16 Neurontin in the 2004-2005 time frame?
 17 A. I'm not aware of any.
 18 Q. Mr. Lanier talked to you about
 19 Exhibit 6, which is, he represented, as an FDA
 20 document. Do you recall that discussion?
 21 A. Yes.
 22 Q. And he showed you I think one page of
 23 this. This is about a hundred and -- I don't
 24 know how many page document. Hundred and
 25 something page document; correct?

1 area of expertise.
 2 Q. Okay. Fair enough.
 3 VIDEOGRAPHER: One minute
 4 remaining.
 5 MR. FERGUSON: Why don't we go
 6 ahead and break real quick since we have
 7 one minute left, and then I'll try to
 8 finish up here quickly.
 9 VIDEOGRAPHER: We're going off
 10 the record. This marks the end of tape
 11 number 1. The time on the monitor is
 12 10:02. Tape number 1. Going off the
 13 record.
 14 (Recess from 10:02 to 10:17 a.m.)
 15 VIDEOGRAPHER: Stand by.
 16 We're coming back on the record.
 17 This marks the beginning of tape number 2.
 18 Time on the monitor is 10:17.
 19 You may proceed, counselor.
 20 Q. (By Mr. Ferguson) Okay, Doctor, we
 21 have taken a break. Are you ready to
 22 proceed?
 23 A. I am.
 24 Q. We were talking a little bit earlier
 25 about the fact that you are aware now that back

1 A. Yes.
 2 Q. Okay. You haven't reviewed the whole
 3 document?
 4 A. No.
 5 Q. Okay. And if as you -- 119 pages. If
 6 as he represented to you this is an FDA
 7 document, the FDA had whatever information was
 8 in here when it approved the Neurontin
 9 labeling; correct?
 10 A. I would assume so.
 11 Q. And I think he asked you if you would
 12 like to have known the information that he
 13 pointed out in there; correct? Do you recall
 14 that?
 15 A. Yeah, any, any relevant information I
 16 would like --
 17 Q. Sure.
 18 A. -- to have available.
 19 Q. And this referred, this document,
 20 Exhibit 6, referred to a suicide attempt that
 21 may have occurred, or suicide in connection
 22 with someone who was on Neurontin; correct?
 23 MR. LANIER: Page 117.
 24 Q. (By Mr. Ferguson) Page 117.
 25 A. Okay. I'm sorry, what was your

1 Q. Including potential suicides?
 2 A. Statistically I'm sure, yes.
 3 Q. Okay. And the population taking
 4 Neurontin are people with pain?
 5 A. Yes.
 6 Q. To your knowledge, epilepsy; correct?
 7 A. Yes.
 8 Q. And do both of those conditions, if you
 9 know, have increased possibility of suicide?
 10 A. I do not know.
 11 Q. Okay. If 12 million people took
 12 Neurontin worldwide, would, would it give you
 13 concern one way or the other if there were 35
 14 suicides reported in connection with that?
 15 MR. LANIER: What do you mean by
 16 "report"?
 17 MR. FERGUSON: Has adverse
 18 events.
 19 MR. LANIER: Are you talking
 20 about like filing those MedWatch things?
 21 MR. FERGUSON: I'm talking about
 22 adverse events reported to the company.
 23 Like to say anything else?
 24 MR. LANIER: Well, he hadn't
 25 even filed a MedWatch. These doctors don't

1 Q. With regard to this gentleman named
 2 David Franklin, who Mr. Lanier talked to you
 3 about, you never met Mr. Franklin, did you, or
 4 Dr. Franklin?
 5 A. No. Again, not that I'm aware of.
 6 Q. And he read, read you some what
 7 purported to be a quote from a guy named Phil
 8 Magistro, a phone conversation or something.
 9 You don't know Mr. Phil Magistro, do you?
 10 A. No.
 11 Q. Given the information you have today
 12 going, going into today, as we discussed,
 13 you're still prescribing Neurontin for some
 14 patients?
 15 A. Selectively, yes.
 16 Q. And my understanding from your
 17 testimony, Mr. Lanier is, based on what you
 18 know today, you don't know one way or the other
 19 whether you would still prescribe for
 20 Mr. Smith, is that accurate?
 21 A. If Mr. Smith came into my office today,
 22 I would not prescribe him Neurontin as -- he
 23 would have gotten Lyrica.
 24 Q. Okay. Lyrica wasn't available in 2004,
 25 was it?

1 do that. You can't even look at those.
 2 But I'll -- I shouldn't be saying that.
 3 I'm saving that for redirect. Go ahead.
 4 MR. FERGUSON: Thank you.
 5 Q. (By Mr. Ferguson) Doctor, if 12
 6 million people took it, would it surprise you
 7 if there were 35 suicides reported in
 8 connection with those 12 million?
 9 A. Probably not. But I would want to know
 10 the details surrounding that.
 11 Q. Sure. Sure. Fair enough. If 12
 12 million people take something and a certain
 13 number of things are going to occur by, by
 14 chance alone; correct?
 15 A. Right. And but you also have to weigh
 16 the relative complications --
 17 Q. Sure.
 18 A. -- to the frequency.
 19 Q. And I take it you're not an expert in
 20 epidemiology, fair enough?
 21 A. Fair enough.
 22 Q. Okay. And with regard to the
 23 epidemiology of suicide, you're specifically
 24 not an expert; correct?
 25 A. No.

1 A. No. Not that I'm aware of. Not that I
 2 recall.
 3 Q. Okay.
 4 MR. FERGUSON: I think that's
 5 all I have for now, Doctor. Thank you very
 6 much.
 7 THE WITNESS: All right.
 8 MR. LANIER: You know, he did
 9 better on time than I thought he was going
 10 to. I got to give it to you.
 11 MR. FERGUSON: Appreciate it.
 12 REDIRECT EXAMINATION
 13 BY MR. LANIER:
 14 Q. I want to go back through some
 15 questions that were just asked of you and make
 16 sure I understand some of the answers, okay?
 17 You were first asked, is it true
 18 that you decide how to treat patients and
 19 nobody tells you how to do it. Do you remember
 20 those questions?
 21 A. Yes, I do remember that question.
 22 Q. Let me understand how you do this,
 23 please. You certainly are the doctor, and you
 24 make your recommendations, is that fair to
 25 say?